SCHEDULE 7

(Annex IV of the ATEX Directive)
MODULE: PRODUCTION QUALITY ASSURANCE

Surveillance under the responsibility of the notified body

4.—(4.1) The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

(4.2) The manufacturer shall, for inspection purposes, allow the notified body access to the manufacture, inspection, testing and storage premises and shall provide it with all necessary information, in particular

— the quality system documentation

— the quality records, such as inspection reports and text data, calibration data, reports on the qualifications of the personnel concerned, etc.

(4.3) The notified body shall periodically carry out audits to ensure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

(4.4) Furthermore, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may carry out tests, or arrange for tests to be carried out, to check that the quality system is functioning correctly, if necessary. The notified body shall provide the manufacturer with a visit report and, if a test has taken place, with a test report.